K032734

APR - 8 2004

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant:	ConvaTec, A Division of E.R. Squibb and Sons, L.L.C. 200 Headquarters Park Drive, Skillman, NJ 08558
Contact:	Nancy Regulski, Regulatory Affairs (908) 904-2721
Device:	ConvaTec Fecal Management System
Substantially Equivalent Device	Indwelling Fecal Management System

The purpose of this 510(k) Premarket Notification is to request clearance to market The ConvaTec Fecal Management System. This product will be labeled as a prescription medic al device.

The ConvaTec Fecal Management System is indicated for the fecal management of patients with little or no bowel control and for patients whose stool is semi-liquid or liquid.

The ConvaTec Fecal Management System is substantially equivalent to Indwelling Fecal Management System, marketed by Bowel Management Systems, LLC, K012113. Both products are classified as *Gastrointestinal tube and accessories*, 21 CFR 876.5980 and are equivalent in design, components, materials, intended use, and indications for use.

The ConvaTec Fecal Management System has been subjected to biocompatibility testing utilizing the ISO 10993 Part I "Biological Evaluation of Medical Devices" with FDA modified matrix (Guidance effective July 1, 1995). The results of this testing demonstrate that The ConvaTec Fecal Management System is considered to be non-sensitizing, non-cytotoxic, and non-irritating.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2004

Ms. Nancy Regulski
Manager, Regulatory Affairs
ConvaTec, A Division of E.R. Squibb and Sons, L.L.C.
200 Headquarters Park Drive
SKILLMAN NJ 08558

Re: K032734
Trade/Device Name: ConvaTec Fecal Management System
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 KNT
Dated: January 21, 2004
Received: January 22, 2004

Dear Ms. Regulski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~Not Known~~ K032734

Device Name: ConvaTec Fecal Management System

Indications for Use:

For the fecal management of patients with little or no bowel control and for patients whose stool is semi-liquid or liquid.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Perscription Use X
(Per 21CFR 801.109)

OR

Over the Counter Use___
(Optimal Format 2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032734